

**IN THE UNITED STATES DISTRICT COURT FOR THE  
DISTRICT OF NEW JERSEY**

IN RE: JOHNSON & JOHNSON )  
TALCUM POWDER PRODUCTS )  
MARKETING, SALES PRACTICES AND )  
PRODUCTS LIABILITY LITIGATION )

MDL Docket No. 2738

## This Document Relates To All Cases

**DEFENDANTS JOHNSON & JOHNSON AND LLT MANAGEMENT,  
LLC'S MEMORANDUM OF LAW IN OPPOSITION TO THE  
PLAINTIFFS' STEERING COMMITTEE'S MOTION TO EXCLUDE THE  
OPINIONS OF DR. JOHN KORNAK**

**FAEGRE DRINKER BIDDLE &  
REATH LLP**

*A Delaware Limited Liability Partnership*

600 Campus Drive  
Florham Park, New Jersey 07932  
(973) 549-7000

**SKADDEN, ARPS, SLATE,  
MEAGHER & FLOM LLP**

One Manhattan West  
New York, NY 10001-8602  
(212) 735-3000

*Attorneys for Defendants Johnson &  
Johnson and LLT Management, LLC*

## **TABLE OF CONTENTS**

	<b><u>Page</u></b>
BACKGROUND .....	2
A.    Dr. John Kornak.....	2
B.    The Sister Study Cohort.....	5
ARGUMENT.....	12
I.    PLAINTIFFS’ ARGUMENT THAT O’BRIEN 2024 SHOULD BE AFFORDED “DEFERENCE” IS NOT A BASIS TO EXCLUDE DR. KORNAK’S OPINIONS. ....	13
II.   DR. KORNAK’S OPINIONS ON O’BRIEN 2024 ARE RELIABLE. ....	18
CONCLUSION .....	24

## TABLE OF AUTHORITIES

### Page(s)

### CASES

<i>In re Abilify (Aripiprazole) Products Liability Litigation,</i> 299 F. Supp. 3d 1291 (N.D. Fla. 2018) .....	16
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.,</i> 43 F.3d 1311 (9th Cir. 1995).....	15
<i>Daubert v. Merrell Dow Pharmaceuticals, Inc.,</i> 509 U.S. 579 (2003).....	13
<i>In re Deepwater Horizon Belo Cases,</i> No. 3:19cv963, 2020 WL 6689212 (N.D. Fla. Nov. 4, 2020).....	14
<i>In re Ethicon, Inc.,</i> MDL No. 2327, 2016 WL 4944702 (S.D. W. Va. Aug. 30, 2016) .....	23
<i>Franco v. Boston Scientific Corp.,</i> No. 2:12-cv-02748, 2016 WL 3248505 (S.D. W. Va. June 13, 2016) .....	23
<i>Goodrich v. John Crane, Inc.,</i> No. 4:17cv9, 2018 WL 4677773 (E.D. Va. Sept. 28, 2018) .....	14
<i>Holbrook v. Lykes Bros. Steamship Co.,</i> 80 F.3d 777 (3d Cir. 1996).....	15
<i>In re Johnson &amp; Johnson Talcum Powder Products Marketing, Sales Practices &amp; Products Litigation,</i> 509 F. Supp. 3d 116 (D.N.J. 2020).....	13
<i>Kolokowski v. Crown Equipment Corp.,</i> No. 05-4257, 2009 WL 2857957 (D.N.J. Aug. 27, 2009).....	13
<i>McBroom v. Ethicon, Inc.,</i> No. CV-20-02127-PHX-DGC, 2021 WL 2709292 (D. Ariz. July 1, 2021) .....	23

<i>In re Mirena IUD Products Liability Litigation</i> , 169 F. Supp. 3d 396 (S.D.N.Y. 2016) .....	16
<i>Valentine v. Pioneer Chlor Alkali Co.</i> , 921 F. Supp. 666 (D. Nev. 1996) .....	14, 15
<i>In re Yasmin &amp; Yaz (Drospirenone) Marketing, Sales Practices &amp; Products Liability Litigation</i> , No. 3:09-md-02100-DRH-PMF, 2011 WL 6302573 (S.D. Ill. Dec. 16, 2011) .....	16
<i>In re Zantac (Ranitidine) Products Liability Litigation</i> , 644 F. Supp. 3d 1075 (S.D. Fla. 2022) .....	14
<i>In re Zyprexa Products Liability Litigation</i> , 489 F. Supp. 2d 230 (E.D.N.Y. 2007) .....	15, 16

## OTHER AUTHORITIES

Chang, <i>Use of Personal Care Product Mixtures and Incident Hormone- Sensitive Cancers in the Sister Study: A U.S.-Wide Prospective Cohort</i> , 183 Environ. Int'l 1 (2024) .....	6
Gates, <i>Talc Use, Variants of the GSTM1, GSTT1, &amp; NAT2 Genes and Risk of Epithelial Ovarian Cancer</i> , 17(9) Cancer Epidemiol. Biomarkers Prev. 2436 (2008) .....	5
Gonzalez, <i>Douching, Talc Use, and Risk of Ovarian Cancer</i> , 27(6) Epidemiology 797 (2016) .....	5, 6, 17
Lock & Smith, <i>What Do Peer Reviewers Do?</i> 263(10) JAMA 1341 (1990) .....	15
O'Brien, <i>Association of Powder Use in the Genital Area with Risk of Ovarian Cancer</i> , 323(1) JAMA 49 (2020) .....	6, 17
O'Brien, <i>Douching and Genital Talc Use: Patterns of Use and Reliability of Self-Reported Exposure</i> , 34(3) Epidemiology 376 (2023) .....	6, 7, 9

- O'Brien, *Intimate Care Products and Incidence of Hormone-Related Cancers: A Quantitative Bias Analysis*, J. Clin. Oncol. (2024): JCO-23..... passim
- White & Royston, *Imputing Missing Covariate Values for the Cox Model*, 28(15) Stats. Med. 1982 (2009)..... 12, 22

Dr. John Kornak, Ph.D. is a professor of biostatistics at the University of California, San Francisco (“UCSF”) with more than 20 years of experience. He intends to testify at trial that O’Brien 2024—a recent epidemiological study relied on by several plaintiffs’ experts—is deeply flawed. As Dr. Kornak explains, O’Brien 2024 does not report a statistically significant association between *reported* talc use and ovarian cancer. The study does report a significant association, however, after adding figures for *imputed* talc use—i.e., after using a model that purports to guess whether women with missing data used cosmetic talc.

In a motion that cites almost no legal authority and is completely untethered to any governing legal standard, plaintiffs have moved to exclude Dr. Kornak’s criticism and discussion of O’Brien 2024. Specifically, plaintiffs argue that O’Brien 2024 “deserve[s] deference,” by which they apparently mean that no one should be allowed to critique it, because it underwent peer review and was published. This position is legally unsupportable and wholly ignores the wealth of (also peer-reviewed and published) scientific evidence that disclaims any association, much less causal relationship, between talcum powder use and ovarian cancer. Plaintiffs also assert that Dr. Kornak’s opinions are unreliable based on the “circumstances” of Dr. Kornak’s retention, his use of “superlatives,” and his supposedly inadequate review of the literature. All of these arguments are meritless. The process by which Dr. Kornak was retained was entirely routine and

a result of the exigencies of the litigation. And despite plaintiffs’ repeated mischaracterizations of Dr. Kornak’s deposition testimony, he made clear in his report and at his deposition that he adequately read and considered scientific authority. In any event, plaintiffs’ criticisms of Dr. Kornak apply with equal (if not greater) force to their own paid experts.

For all of these reasons, discussed in more detail below, the Court should deny plaintiffs’ motion.

### **BACKGROUND**

#### **A. Dr. John Kornak**

Dr. John Kornak is a professor of biostatistics, with more than 20 years of academic experience since receiving his Ph.D. in statistics.<sup>1</sup> He is currently a Professor in Residence of Biostatistics in the Department of Epidemiology and Biostatistics at the School of Medicine at UCSF, the Head of the Health Data Science Program at UCSF, and the Director of the UCSF Biostatistics Consulting Unit.<sup>2</sup> Dr. Kornak has received numerous honors and awards in his long career in the field of biostatistics, most recently being selected as a fellow of the American Statistical Association.<sup>3</sup> He also currently is the lead statistician on several large-

---

<sup>1</sup> (Rep. of John Kornak (“Kornak Rep.”) at 1, May 28, 2024 (Pls.’ Br. Ex. 5).)

<sup>2</sup> (*Id.*)

<sup>3</sup> (*Id.* at 2.)

scale collaborative research projects, which include observational studies, clinical research projects, and clinical trials.<sup>4</sup> Additionally, Dr. Kornak has created and taught masters'-level programs and classes in biostatistics and supervises graduate students and faculty members in the fields of biostatistics, epidemiology, and clinical research training.<sup>5</sup> Dr. Kornak has authored and published more than 150 peer-reviewed publications, book chapters and review articles.<sup>6</sup> He has used multiple imputation in some of those peer-reviewed publications.<sup>7</sup>

Dr. Kornak opines that the O'Brien 2024 study, which purported to find "a positive and statistically significant association between genital talc use (based on . . . adjustments) and ovarian cancer," was "drive[n]" by the authors' "inclusion of retrospective information on genital talc use" that "imputes" and/or "assumes the genital talc use of large subsets of women to account for missing or contradictory data . . . ."<sup>8</sup> Dr. Kornak identifies seven reasons why the O'Brien

---

<sup>4</sup> (*Id.* at 1.)

<sup>5</sup> (*Id.*)

<sup>6</sup> (*Id.* at 2.)

<sup>7</sup> (Dep. of John Kornak ("Kornak Dep.") 93:17-23, July 8, 2024 (Pls.' Br. Ex. 6); *id.* 408:18-21.) Although plaintiffs claim Dr. Kornak "backtracked" when asked if he had written on multiple imputations in his published articles, this is demonstrably false. Dr. Kornak made clear that he "definitely . . . addressed questions about imputation in publications" but simply did not cite to his own published literature in his expert report because "they're not the most appropriate references to cite for supporting [his] opinions." (*Id.* 95:10-97:2.)

<sup>8</sup> (Kornak Rep. at 3.)



2024 “analysis [is] flawed and unreliable.” As he explains: (1) it “hinges on the authors’ reclassification of women who never indicated genital talc use as genital talc users”; (2) “imputation” of genital talc data “exacerbates the ‘recall bias’ problem”; (3) the “chosen imputation method is inappropriate for the dataset”; (4) “‘imputed’ genital talc use is likely a poor proxy for a woman’s actual genital talc use”; (5) “‘imputations’ of genital talc use rely on circular logic”; (6) an “unreliably large share of the authors’ data on genital talc use” is assumed; and (7) the assumed genital talc use data “rely on inconsistent questions across Sister Study enrollment and follow-up questionnaires.”<sup>9</sup>

Dr. Kornak further explains that the flawed “imputations” in O’Brien 2024 “inflated” the estimated association between talc and ovarian cancer.<sup>10</sup> Dr. Kornak also opines that O’Brien 2024’s “analysis of how recall bias affects their estimate of the association between genital talc use and ovarian cancer is flawed and unreliable.”<sup>11</sup> In support of these opinions, Dr. Kornak cited 12 scientific articles or books (in addition to O’Brien 2024 itself), and 6 different public sources of data.<sup>12</sup>

---

<sup>9</sup> (*Id.* at 3-4.)

<sup>10</sup> (*Id.* at 31-33.)

<sup>11</sup> (*Id.* at 35-37.)

<sup>12</sup> (App. B to Kornak Rep. at 1-2.)

## **B. The Sister Study Cohort**

The Sister Study is a cohort study of more than 50,000 women aged 35 to 74 years at enrollment who had sisters who were diagnosed with breast cancer and were therefore “more likely than the general population to develop ovarian cancer.”<sup>13</sup> Participants were asked at enrollment about personal products used in the 12 months prior to enrollment and at ages 10-13, including questions about method of cosmetic talc use, frequency of cosmetic talc use, and douching.<sup>14</sup> It is unlikely any substantial number of participants began using cosmetic talc after enrollment, since 95% of talc users start before 35 (the age of the youngest participant at enrollment).<sup>15</sup>

Several studies have reported on the Sister Study cohort data and, until this one, they unanimously concluded that there is no association between talcum powder use and ovarian cancer. For example:

- Gonzalez 2016 was the first article that reported on the Sister Study. After 6.5 years of follow-up, it reported no significant association between talc use and ovarian cancer (and, in fact, a non-significant

---

<sup>13</sup> Gonzalez, *Douching, Talc Use, and Risk of Ovarian Cancer*, 27(6) *Epidemiology* 797, 797, 800 (2016) (“Gonzalez 2016”) (Pls.’ Br. Ex. 11).

<sup>14</sup> *Id.* at 798.

<sup>15</sup> See Gates, *Talc Use, Variants of the GSTM1, GSTT1, & NAT2 Genes and Risk of Epithelial Ovarian Cancer*, 17(9) *Cancer Epidemiol. Biomarkers Prev.* 2436 (2008) (Ex. 1 to Decl. of Jessica Davidson (“Davidson Decl.”)). (See also Pls.’ Br. at 9 (citing study results “that the average age at first use was 21.0 years).)

protective effect) among study subjects.<sup>16</sup>

- O'Brien 2020 utilized data from four cohorts—including data from the Sister Study with a longer follow-up period than Gonzalez<sup>17</sup>—and found “no statistically significant association between . . . use of [talcum] powder in the genital area and risk of ovarian cancer.”<sup>18</sup>
- Chang 2024, based on data reported in the Sister Study cohort, found a non-significant association between ovarian cancer and vaginal talc use.<sup>19</sup>

In addition to these studies, as part of an effort to “evaluate the reliability of self-reported data,” O'Brien 2023 “collected retrospective data on douching and genital talc use in the” Sister Study via a fourth follow-up questionnaire.<sup>20</sup> The authors found that while most women were more likely to report talc use at enrollment than follow-up, for women who had been diagnosed with cancer in the

---

<sup>16</sup> Gonzalez 2016 at 800-02 (HR 0.73 (95% CI: 0.44-1.2)).

<sup>17</sup> The median follow-up period in O'Brien was 11.2 years. With respect to the subset of data from the Sister Cohort, the median follow-up time was 9.6 years.

<sup>18</sup> O'Brien, *Association of Powder Use in the Genital Area with Risk of Ovarian Cancer*, 323(1) JAMA 49, 56 (2020) (“O'Brien 2020”) (Ex. 2 to Davidson Decl.). The estimated HR for long-term use vs never use was 1.01 (95% CI: 0.82-1.25), with a non-statistically significant estimated HR of 1.09 (95% CI: 0.97-1.23) for frequent vs never users. *Id.* at 55 tbl. 3.

<sup>19</sup> See Chang, *Use of Personal Care Product Mixtures and Incident Hormone-Sensitive Cancers in the Sister Study: A U.S.-Wide Prospective Cohort*, 183 Environ. Int'l 1 (2024) (Ex. 3 to Davidson Decl.) (HR of 1.04; 95% CI (0.91, 1.19)).

<sup>20</sup> O'Brien, *Douching and Genital Talc Use: Patterns of Use and Reliability of Self-Reported Exposure*, 34(3) Epidemiology 376, 376 (2023) (“O'Brien 2023”) (Ex. 4 to Davidson Decl.). Plaintiffs refer to this as the “2023 Douching Study.”

interim, “the trend was reversed” and “[t]his was the only subgroup for which the proportion of [reported] users increased between enrollment and follow-up.”<sup>21</sup>

That shows “recall bias (i.e., over-reporting of talc use among those with a history of ovarian cancer),” which the authors state could explain why many retrospective studies have not shown an association, while prospective studies have.<sup>22</sup>

The most recent study from this Cohort, O’Brien 2024, was published on May 15. Plaintiffs brought it to the attention of defendants and the Court on May 17. At the time expert reports were due on May 21. The parties all agreed on the need to extend that date to allow some time to account for the new paper.

Defendants proposed that plaintiffs’ experts provide reports by May 28, sit for brief depositions, and defendants’ experts provide reports by June 14. Plaintiffs proposed, and the Magistrate Judge adopted, a schedule under which all expert reports were due on May 28. Thus, all the experts in this litigation, including Dr. Kornak, put together reports accounting for O’Brien 2024 within two weeks of the article’s publication.

Like the 2023 study, O’Brien 2024 also sought to rely on retrospective

---

<sup>21</sup> *Id.* at 383.

<sup>22</sup> *Id.* (“may indicate recall bias is present and potentially driving some of the previously observed differences in effect estimates between studies collecting genital powder exposure status retrospectively versus prospectively”). Plaintiffs’ claim that the article found “limited evidence” evidence of recall bias (Pls.’ Br. at 10) is flatly incorrect.

surveys to obtain more information on talc use from women in the Sister Study, but many respondents either provided contradictory responses or failed to respond to the follow-up survey.<sup>23</sup> In an effort to address the significant amount of missing data, O’Brien 2024 modeled various scenarios using data that were largely “corrected” or “imputed”<sup>24</sup>—i.e., made up. Importantly, when the O’Brien authors looked at actual prospective data they were able to collect, they noted—consistent with previous scientific literature—that there was no association between talc and ovarian cancer (HR: 1.02, 95% CI: 0.79-1.33).<sup>25</sup>

Corrections for “contradictory” data were performed on two groups of women. The first group included women who reported using talc at enrollment and then reported never-use at follow up. The authors randomly selected 90% of this group to be treated as exposed (i.e., they prioritized the enrollment report).<sup>26</sup> The second group initially reported not using talc between the ages of 10-13 or the

---

<sup>23</sup> O’Brien, *Intimate Care Products and Incidence of Hormone-Related Cancers: A Quantitative Bias Analysis*, J. Clin. Oncol. (2024): JCO-23, at 3 (“O’Brien 2024”) (Pls.’ Br. Ex. 1) (“Data on intimate care product use were sometimes contradictory or missing.”).

<sup>24</sup> *Id.* (O’Brien 2024 authors noting that they “used quantitative bias analyses to implement different approaches for imputing exposure in women who initially reported never use but did not complete the follow-up questionnaire”); *id.* at 4 (O’Brien 2024 authors describing their analysis as including “contradictory data correction with multiple imputation of missing or undefined data”).

<sup>25</sup> *Id.* at tbl. A2.

<sup>26</sup> *Id.* at tbl. A5.

year before enrollment and then reported at follow-up that they had used talc at the time of enrollment.<sup>27</sup> The authors randomly selected 80% of this group to be treated as exposed (i.e., they prioritized the follow-up report).<sup>28</sup> The authors do not explain either of these decisions, both of which assume that for the vast majority of women, whenever they said they used talc they must have been right, and whenever they said they did not, they must have been wrong. The second correction—that 80% of those who reported nonuse and then use were wrong at enrollment and correct at follow up—is particularly illogical and inconsistent with the authors’ prior paper, in which they stated that “[b]ecause enrollment was more proximate to th[e] referent time period, [they] consider use reported on the enrollment questionnaire to be the ‘gold standard.’”<sup>29</sup> Thus, the choices made in the data “correction” process likely overstated the exposed population.<sup>30</sup> After these corrections, the hazard ratio was very slightly elevated but still non-significant (HR: 1.17, 95% CI: 0.92-1.49).<sup>31</sup>

Next, the authors sought to account for the fact that 28% of participants, and

---

<sup>27</sup> Women who initially reported nonuse and then reported use at ages other than 10-13 or the year before enrollment were coded as 100% exposed.

<sup>28</sup> *Id.*

<sup>29</sup> O’Brien 2023 at 377.

<sup>30</sup> This is true even in the authors’ “Scenario 2,” which they incorrectly refer to as “extreme unexposed.”

<sup>31</sup> O’Brien 2024 at 7 tbl. 2, Scenario 2.

an even greater portion of ovarian cancer cases, did not respond to the follow-up survey on talc use.<sup>32</sup> That included 6% of survey respondents who reported use at enrollment and who were all classified as users on that basis. It also included 21% who reported non-use at enrollment, and 1% who did not respond at enrollment either. In the model on which the authors based their conclusions,<sup>33</sup> they used multiple imputation to estimate the portion of missing respondents who likely would have reported talc use, based on a model of demographic and confounding factors (e.g., race, body mass index (“BMI”), and parity).

As with their “corrections,” in constructing their imputed results, the authors made choices that systematically overestimated levels of talc use for women with missing data. In particular, because the imputation model was applied to women who had reported no talc use in the prospective survey, almost all the women who were classified as talc users under the imputation had originally denied talc use with respect to the only period about which they were asked.<sup>34</sup> To be sure, it is possible that those women used talc at times other than those covered by the initial survey, but their previous report of nonuse represents a critical data point that makes them systematically less likely to have been talc users, something the

---

<sup>32</sup> See *id.* at tbl. A5 (rows 4, 8, and 12).

<sup>33</sup> Scenario 4, which the authors call the “best estimate.”

<sup>34</sup> As mentioned, women who initially reported talc exposure and failed to respond to follow-up were coded as exposed. (See Kornak Rep. at 33.)

imputation model ignored altogether. Moreover, because the women for whom data were missing had higher rates of cancer, inflating the likelihood they were exposed to talc “add[ed] a disproportionate share of ovarian cancer cases to the group of genital talc users”<sup>35</sup> and therefore inflated the resulting association.

When the results of this model were combined with the real data, the authors reported a statistically significant association with ovarian cancer, and one that is implausibly high, since it is substantially stronger than had been reported in almost any prior epidemiological study (HR: 1.82, 95% CI: 1.36-2.43). This stems entirely from the modeled results, since, as discussed, there was no association among the 72% of respondents for whom complete results were available.<sup>36</sup> Critically, those modeled results were obtained by predicting talc use from *confounding* factors (e.g., BMI), meaning that even if they reliably suggested an association, they would be consistent with a non-causal association. Perhaps for that reason among others, the O’Brien 2024 authors cautioned that the “results do not establish causality and do not implicate any specific cancer-inducing agent.”<sup>37</sup>

---

<sup>35</sup> (*Id.* at 32.)

<sup>36</sup> The results of the multiple imputation model alone are not separately reported, but to obtain a hazard ratio of 1.82 when the reported data showed no association would require that the odds ratio among missing women whose results were imputed be extremely high—much higher than anything previously reported. No explanation has been reported for such an implausible finding.

<sup>37</sup> O’Brien 2024 at 13.



The authors also noted that their data were collected (or constructed) after cancer diagnosis and thus “allow[ed] for the possibility of recall bias.”<sup>38</sup> The authors tried to address this limitation by recalculating their modeled results for several recall bias “scenarios.” For instance, if 25% of the women with ovarian cancer who either reported talc use or were modeled as talc users were actually nonusers, the reported association would fall by half. If 50% of those women were really nonusers, the reported association would disappear.<sup>39</sup>

### **ARGUMENT**

Plaintiffs seek to exclude Dr. Kornak’s opinions about the O’Brien 2024 study on the basis that the study was subject to the peer-review process and ultimately published, which they believe renders the paper unassailable. Plaintiffs further argue that Dr. Kornak’s opinions are unreliable because he reached them after being retained in litigation, used “superlatives,” did not adequately review the literature (apparently because he did not cite an article by White and Royston in his report,<sup>40</sup> even though he testified that he considered the article), and did not adopt

---

<sup>38</sup> *Id.* at 14. The study results show this risk was not just theoretical. The HR calculated from fully prospective enrollment data show no increased risk (HR: 1.02, 95% CI: 0.79-1.33), while the “mostly retrospective” data show substantially increased risk (HR: 2.65, 95% CI 1.91-3.70). O’Brien 2024 at tbl. A2.

<sup>39</sup> *Id.* at 9 fig. 2.

<sup>40</sup> White & Royston, *Imputing Missing Covariate Values for the Cox Model*, 28(15) *Stats. Med.* 1982 (2009) (“White & Royston 2009”) (Pls.’ Br. Ex. 14).

White and Royston’s supposed view that cancer status should be included as a predictor for talc use. Plaintiffs fail to cite any supporting authority for these arguments. As such, and for the reasons set forth below, plaintiffs’ motion to exclude Dr. Kornak’s opinions should be denied.

**I. PLAINTIFFS’ ARGUMENT THAT O’BRIEN 2024 SHOULD BE AFFORDED “DEFERENCE” IS NOT A BASIS TO EXCLUDE DR. KORNAK’S OPINIONS.**

Plaintiffs first argue that since O’Brien 2024 was subject to the peer-review process, it is entitled to “deference,” which apparently means it cannot be questioned. (See Pls.’ Br. at 20-22.) For starters, O’Brien 2024 should not be afforded “deference” by this Court for all the reasons explained above, but that is beside the point for this motion. The key point here is that peer review by itself *“does not equate with reliability.”* *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Pracs. & Prods. Litig.*, 509 F. Supp. 3d 116, 143 (D.N.J. 2020) (emphasis added) (citation omitted) (passage quoted in Pls.’ Br. at 20);<sup>41</sup> *see also*

---

<sup>41</sup> The Supreme Court’s decision in *Daubert* (one of plaintiffs’ few citations) fails to support their position. Rather than proclaiming that peer-reviewed science is *per se* unassailable, the Court held the exact opposite: “[t]he fact of publication (or lack thereof) in a peer reviewed journal thus will be a relevant, ***though not dispositive***, consideration in assessing the scientific validity of a particular technique or methodology.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 594 (2003) (emphasis added). And *Kolokowski v. Crown Equipment Corp.* holds only that “the dearth of peer reviewed literature counsel[ed] against the admission” of an opinion, not that peer-reviewed opinions are necessarily reliable or correct. No. 05-4257, 2009 WL 2857957, at \*10 (D.N.J. Aug. 27, 2009).

*In re Zantac (Ranitidine) Prods. Liab. Litig.*, 644 F. Supp. 3d 1075, 1171-73 (S.D. Fla. 2022) (“acceptance in the scientific community and peer review are not necessarily sufficient to establish the reliability of a scientific methodology”); *In re Deepwater Horizon Belo Cases*, No. 3:19cv963, 2020 WL 6689212, at \*12 (N.D. Fla. Nov. 4, 2020) (excluding expert who failed to critically evaluate and critique studies and instead “relied on . . . the fact that the studies were all peer reviewed and published” because “it is well established that ‘publication is not a *sine qua non* of admissibility’”) (citations omitted); *Goodrich v. John Crane, Inc.*, No. 4:17cv9, 2018 WL 4677773, at \*23 (E.D. Va. Sept. 28, 2018) (rejecting argument that study was reliable simply because it “ha[d] been peer reviewed” and “published”) *Valentine v. Pioneer Chlor Alkali Co.*, 921 F. Supp. 666, 674-78 (D. Nev. 1996) (finding peer-reviewed study to “suffer[] from very serious flaws” such that it could not “be said to be derived from acceptable scientific methodology”). As one court noted, “the pre-publication ‘peer review’ of scientific writings is of much narrower scope” than “true peer review,” which happens after publication when other scientists attack, support, and seek to replicate the paper’s findings. *Valentine*, 921 F. Supp. at 675. “[I]t is a serious error to conflate the two processes, and, by extension, to assume that because an article is accepted for publication, even in a prestigious scientific journal, that the science it contains is therefore

valid.” *Id.*<sup>42</sup> O’Brien 2024 should be critically evaluated on its merits, not presumed reliable (much less correct) simply because it was published.

Moreover, even if the fact of pre-publication peer review might support the admissibility of an expert opinion based on the article, it does not follow that such review precludes the admission of a contrary opinion. Plaintiffs essentially advocate for a rule that once an opinion has been published, it cannot be challenged in court. That is not the law, because “[p]eer review and publication do not, of course, guarantee that the conclusions reached are correct; much published scientific research is greeted with intense skepticism and is not borne out by further research.” *Daubert v. Merrell Dow Pharms., Inc.*, 43 F.3d 1311, 1318 (9th Cir. 1995).

Critiques of the peer-reviewed literature are particularly appropriate for defense experts like Dr. Kornak. “[T]he defense d[oes] not bear” the burden of proof on causation. *Holbrook v. Lykes Bros. S.S. Co.*, 80 F.3d 777, 786 (3d Cir. 1996); *see also In re Zyprexa Prods. Liab. Litig.*, 489 F. Supp. 2d 230, 285 (E.D.N.Y. 2007) (“[D]efendants’ experts have a less demanding task, since they have no burden to produce models or methods of their own; they need only attack

---

<sup>42</sup> Plaintiffs seem incredulous that Dr. Kornak might believe the peer reviewers missed certain biostatistical flaws, but “the average referee spends less than two hours assessing an article submitted to a biomedical journal.” *Valentine*, 921 F. Supp. at 675 (citing Lock & Smith, *What Do Peer Reviewers Do?* 263(10) JAMA 1341 (1990)).

those of plaintiffs' experts."). Thus, it is "entirely appropriate" for a defense expert to offer opinions that are "essentially, critiques of [p]laintiffs' experts' *evidence*, methodologies, and conclusions." *In re Abilify (Aripiprazole) Prods. Liab. Litig.*, 299 F. Supp. 3d 1291, 1368 (N.D. Fla. 2018) (emphasis added). This includes "pointing to . . . the weaknesses of [the peer-reviewed] studies on which [p]laintiffs rely." *In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 418-19 & n.14 (S.D.N.Y. 2016) (permitting defense expert to opine that a peer-reviewed study published in the International Journal of Women's Health, on which plaintiffs' experts relied, "suffer[ed] from multiple methodological and analytical flaws that render its conclusions inaccurate") (citation omitted); *In re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, 2011 WL 6302573, at \*14 (S.D. Ill. Dec. 16, 2011) (permitting expert to "critique flaws in [published epidemiological] studies" in light of his experience); *see also In re Zyprexa*, 489 F. Supp. 2d at 289-90 (holding that defense experts' criticism of "existing mechanistic studies" was admissible).

This is precisely what Dr. Kornak did in this case. The O'Brien 2024 study is subject to a number of "important limitation[s]," some of which the authors acknowledge<sup>43</sup> and others of which they paper over or ignore. Dr. Kornak reliably

---

<sup>43</sup> O'Brien 2024 at 14.

and appropriately pointed these out using his extensive statistical expertise and citation to supporting authority.<sup>44</sup>

Finally, plaintiffs' arguments essentially demonstrate why their own experts' opinions should be excluded. After all, plaintiffs' experts, too, repeatedly critique, and sometimes outright reject, the literature that fails to support their position. Most obviously, they reject the results of published cohort studies showing no association, claiming they are methodologically flawed due to insufficient statistical power or follow-up time.<sup>45</sup> Those studies include O'Brien 2020, the largest study of cohort data ever performed on the issue, which found "no statistically significant association between . . . use of [talcum] powder in the genital area and risk of ovarian cancer,"<sup>46</sup> and Gonzalez 2016, which found no significant association and a non-significant inverse association between talc use and ovarian cancer among study subjects.<sup>47</sup> Plaintiffs' experts' rejection of these studies is far more significant than Dr. Kornak's criticism of O'Brien 2024, since plaintiffs bear the burden of proof, and cannot rest on merely identifying flaws in the evidence.

---

<sup>44</sup> (See generally Kornak Rep.; see also App. B to Kornak Rep.)

<sup>45</sup> (See generally Defs.' Mem. of Law in Supp. of Mot. to Exclude Pls.' Experts' General Causation Ops. at 49-58 (ECF No. 33008-2).)

<sup>46</sup> O'Brien 2020 at 56.

<sup>47</sup> Gonzalez 2016 at 800-02 (HR 0.73; 95% CI: 0.44-1.2).

For all of these reasons, there is no basis beyond plaintiffs' say-so to give O'Brien 2024 so much "deference" as to prevent Dr. Kornak from offering context and criticism.

## **II. DR. KORNAK'S OPINIONS ON O'BRIEN 2024 ARE RELIABLE.**

Plaintiffs also argue that Dr. Kornak's opinions are "biased and not reliable." (Pls.' Br. at 22.) Specifically, plaintiffs claim that Dr. Kornak's opinions are "unsupported" because: (1) he was retained as an expert "before he fully read O'Brien 2024" (*id.* at 16, 22); (2) his report contains language that is not to their liking; (*id.*); and (3) he purportedly "failed to read key papers," particularly one by White and Royston, and disagreed with White and Royston on one issue (*id.* at 23-25). Plaintiffs' arguments lack any basis in the record or the law.

**First**, plaintiffs' assertion that Dr. Kornak's opinions are unreliable because of the "circumstances surrounding Dr. Kornak's report"—i.e., that he was retained as an expert "before he fully read O'Brien 2024" and reached his expert opinion eight days after being retained (Pls.' Br. at 16-17, 22)—is baseless. Many experts, maybe most, lack a firm conclusion about a subject at the time they are first retained or first speak to counsel. Since Dr. Kornak spoke to counsel the very week O'Brien 2024 was published, he is one of them. That is fine because at the time he first met with counsel he was not tasked with reaching any specific conclusion or expected to automatically support defendants' litigation position, but

rather, was asked “to review the O’Brien (2024) paper and then write a report on [his] review of that paper, and that review was an independent review of the paper.”<sup>48</sup>

Plaintiffs also suggest that Dr. Kornak “formulated his opinion” “[w]ith the involvement of . . . J&J’s legal team and Cornerstone.” (Pls.’ Br. at 22; *see id.* at 19.) In fact, Dr. Kornak repeatedly testified that he formed his opinion independently, but even if he did have contact with counsel, that practice would be similar to plaintiffs’ retention of their own expert witnesses. For example, plaintiffs’ expert Dr. Michele Cote recently testified that she spoke to plaintiffs’ counsel multiple times prior to forming her opinion that talc use causes ovarian cancer.<sup>49</sup> And although plaintiffs attempt to cast Dr. Kornak’s report as “hastily drafted” because he completed it over a span of eight days (Pls.’ Br. at 16),<sup>50</sup> plaintiffs’ own experts formed new opinions and amended their reports or drafted entirely new addenda to address O’Brien 2024, in the exact same period of time.<sup>51</sup> There was no other option. The paper was published on May 15, plaintiffs brought

---

<sup>48</sup> (Kornak Dep. 23:14-24:1.)

<sup>49</sup> (Dep. of Michele L. Cote 14:5-15:9, Mar. 21, 2024 (Ex. 5 to Davidson Decl.).)

<sup>50</sup> Plaintiffs also fail to recognize that Dr. Kornak dedicated almost 72 hours to work on his report over the span of eight days, which is far from “hasty.” (*See* Pls.’ Br. Ex. 4.)

<sup>51</sup> (*See, e.g.*, Addendum to Rep. of Bernald L. Harlow, May 28, 2024 (Ex. 6 to Davidson Decl.).)



it to the attention of the Court and defendants on May 17, and the Court set the deadline for expert reports on May 28.<sup>52</sup>

**Second**, plaintiffs take issue with Dr. Kornak’s report on the supposed ground that it “is chock full of superlatives,” by which they apparently mean adjectives. (Pls.’ Br. at 22 (criticizing use of the terms “flawed,” “contrived,” and “vacuous”); *id.* at 16 (referring to the same terms as “nonscientific phrases”).) Plaintiffs do not provide any caselaw supporting the notion that an expert’s opinion should be excluded for using adjectives or ones that express too strong an opinion, which is presumably because none exists. Plaintiffs’ stylistic critique of Dr. Kornak’s word choice has absolutely nothing to do with Rule 702 or *Daubert*. And notably, although plaintiffs take issue with Dr. Kornak’s use of words such as “flawed,” “contrived” or “vacuous” for apparently being too vituperative (Pls.’ Br. at 22), they do not actually dispute that much of the data in O’Brien 2024 was, in fact, “contrived.”

**Lastly**, plaintiffs’ accusation that Dr. Kornak’s opinion is unreliable because he “failed to read key papers” (*id.* at 23) is based on a misrepresentation of Dr. Kornak’s actual testimony. For example, plaintiffs claim that Dr. Kornak is “not

---

<sup>52</sup> At noted above, plaintiffs successfully opposed defendants’ proposal that defense experts be given additional time to prepare reports after O’Brien 2024. It is highly disingenuous to now complain that an expert moved too quickly to comply with the deadline they asked for.

sure if he has ‘ever read [O’Brien 2024] from start to finish.’” (Pls.’ Br. at 16 (quoting Kornak Dep. 26:4-23, 48:24-49:12).) But Dr. Kornak actually testified that he “can’t say whether [he] read every piece of that paper on the first day [of receiving it] or not”<sup>53</sup> and that he did not read it “start to finish,” in the sense that he did not read it sequentially, but rather jumped around.<sup>54</sup> At no point did Dr. Kornak testify that there is any portion of O’Brien 2024 he failed to read, much less any portion remotely relevant to the imputation model he critiques.

Plaintiffs also heavily criticize Dr. Kornak for not “read[ing] O’Brien 2024’s [supposed] justification for including cancer status in their imputation model”—the White and Royston article. (Pls.’ Br. at 25; *see also id.* at 18.) But Dr. Kornak testified that he *did* look at White and Royston,<sup>55</sup> though he did not “go through it in detail” because “it’s kind of a tangential” and because the O’Brien 2024 authors are not “referencing this paper . . . to justify [their] incomplete data.”<sup>56</sup>

---

<sup>53</sup> (Kornak Dep. 26:4-23 (emphasis added).)

<sup>54</sup> (*Id.* 49:7-12 (“start to finish” is “just not the way people tend to approach academic papers”); *see id.* 26:20-21 (“I often jump around and then I often fill in the pieces.”).)

<sup>55</sup> (*Id.* 320:15-21; *id.* 315:5-9 (“Q. And not only do they cite the [White and Royston] paper, you have it on your reliance list, correct, not reliance list, but a paper you considered? A. Yes.”); *id.* 317:3-13 (Dr. Kornak testifying that “like I said, I looked at [the White and Royston paper], I saw what the kind of point of the referencing it was”).)

<sup>56</sup> (*Id.* 320:23-321:13.)

Relatedly, plaintiffs claim that White and Royston demonstrates that Dr. Kornak's opinion that O'Brien 2024 should not have included cancer status in the imputation model is "demonstrably wrong" and "sloppy." (Pls.' Br. at 18, 23-25.) That is not so, for reasons Dr. Kornak explained at his deposition. For starters, Dr. Kornak explained that the O'Brien 2024 authors included a citation to White and Royston "for the method of using the crude cumulative hazard estimate," not to "justify [the] use of the outcome" in the imputation model.<sup>57</sup> (Pls.' Br. at 25.) In addition, the quote from White and Royston cited in plaintiffs' brief—"[w]hen the incomplete data are covariates in the analysis model, the analysis model outcome must be used to predict the missing covariate values" (*id.* (quoting White & Royston 2009 at 1983))—refers to "simulations under ideal missing[-]at[-]random situations" that lack "bias in their outcomes."<sup>58</sup> The paper itself says as much: "[w]e assume throughout that the data are missing at random or missing completely at random."<sup>59</sup> Here, by contrast, the missing data in O'Brien 2024 are not at random (i.e., unrelated to the missing values); instead, the likelihood of missingness is correlated with the likelihood of cancer. As such, Dr. Kornak

---

<sup>57</sup> (See *id.* 321:14-322:13.)

<sup>58</sup> (*Id.* 336:4-9; see *id.* 335:2-5 ("under the assumption that missing multiple imputation is appropriate, which is the missing at random situation"), 335:10-12 ("[Y]ou can't use multiple imputation if you're missing not at random."), 335:16-19 (similar).)

<sup>59</sup> White & Royston 2009 at 1283.

explained there are “biased data that you’re building your imputation model from, you’re going to incorporate that bias into your imputation.”<sup>60</sup>

In short, a review of Dr. Kornak’s deposition demonstrates that he did consider the White and Royston article, and explained why it does not undermine his opinion. For this reason, too, plaintiffs’ arguments lack merit. *See, e.g., Franco v. Bos. Sci. Corp.*, No. 2:12-cv-02748, 2016 WL 3248505, at \*25 (S.D. W. Va. June 13, 2016) (declining to exclude defense expert for allegedly ignoring a study because the defense expert explained at deposition “why he did not believe the study was relevant or contrary to his opinion”); *McBroom v. Ethicon, Inc.*, No. CV-20-02127-PHX-DGC, 2021 WL 2709292, at \*4 (D. Ariz. July 1, 2021) (“Plaintiff’s assertion that [the expert] simply ignored the referenced articles without explanation is not entirely correct” because the expert “explained why he found certain articles less relevant . . . than the literature on which he bases his opinions.”).<sup>61</sup>

---

<sup>60</sup> (Kornak Dep. 334:12-336:9.)

<sup>61</sup> *See also In re Ethicon, Inc.*, MDL No. 2327, 2016 WL 4944702, at \*3 (S.D. W. Va. Aug. 30, 2016) (denying plaintiffs’ motion to exclude certain opinions of defendants’ expert because “[d]uring his deposition or in his report, Dr. Schwartz explained why he did not rely on or discounted the studies the plaintiffs claim he should have reviewed or he actually cited the source”).

**CONCLUSION**

For the foregoing reasons, the Court should deny plaintiffs' motion to exclude the opinions of Dr. Kornak.

Dated: August 22, 2024

Respectfully submitted,

/s/ Susan M. Sharko

Susan M. Sharko

**FAEGRE DRINKER BIDDLE &  
REATH LLP**

Allison M. Brown

Jessica Davidson

**SKADDEN, ARPS, SLATE,  
MEAGHER & FLOM LLP**

*Attorneys for Defendants Johnson &  
Johnson and LLT Management, LLC*